October 30, 2020

Radformation, Inc.
% Mr. Kurt Sysock
Co-founder/CEO
335 Madison Avenue, 16th Floor
NEW YORK NY 10017

Re: K200323
Trade/Device Name: AutoContour
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QKB
Dated: September 19, 2020
Received: September 22, 2020

Dear Mr. Sysock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200323

Device Name
AutoContour

Indications for Use *(Describe)*

AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5. 510(k) Summary

This 510(k) Summary has been created per the requirements of the Safe Medical Device Act (SMDA) of 1990, and the content is provided in conformance with 21 CFR Part 807.92.

5.1. Submitter's Information

Table 1 : Submitter's Information	
Submitter's Name:	Kurt Sysock
Company:	Radformation, Inc.
Address:	335 Madison Avenue, 16th Floor New York, NY 10017
Contact Person:	Alan Nelson Chief Science Officer, Radformation
Phone:	518-888-5727
Fax:	---------
Email:	anelson@radformation.com
Date of Summary Preparation	9/16/2020

5.2. Device Information

Table 2 : Device Information	
Trade Name:	AutoContour
Common Name:	AutoContour, AutoContouring, AutoContour Agent, AutoContour Web Application
Classification Name:	Class II
Classification:	Picture archiving and communications system
Regulation Number:	892.2050
Product Code:	QKB
Classification Panel:	Radiology

5.3. Predicate Devices Information

Mirada RTx (K130393) & Workflow Box (K181572)

5.4. Device Description

AutoContour consists of 3 main components:

1. An “agent” service designed to run on the Windows Operating System that is configured by the user to monitor a network storage location for new CT datasets that are to be automatically uploaded to:
2. A cloud-based AutoContour automatic contouring service that produces initial contours and
3. A web application accessed via web browser which allows the user to perform registration with other image sets as well as review, edit, and export the structure set containing the contours.

5.5. Indications for Use

AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.

5.6. Technological Characteristics

AutoContour (Subject Device) makes use of a Predicate Devices, Mirada RTx (K130393) & Workflow Box (K181572) for substantial equivalence comparison. **Note that Workflow Box utilizes Mirada RTx as its predicate device**.

5.6.1. AutoContour vs. Mirada RTx (K130393) & Workflow Box (K181572)

RTx is “intended to display and visualize 2D & 3D multi-modal medical image data” and “supports the loading and saving of DICOM RT objects and allows the user to define, import, display, transform, store and export such objects including regions of interest structure and dose volumes to radiation therapy planning systems” (https://www.accessdata.fda.gov/cdrh_docs/pdf13/K130393.pdf, accessed 1/20/2020).

Workflow Box “is a system designed to allow users to route DICOM-compliant data to and from automated processing components… [including] processing components for automatically contouring imaging data using … machine learning based algorithms.” (https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181572.pdf, accessed 1/20/2020)

Table 3: Substantial Equivalence AutoContour vs. RTx & Workflow Box

Characteristic	Subject Device: AutoContour Radformation	Predicate Device: Workflow Box (K181572)	Predicate Device: Mirada RTx (K130393)
Target Population	Any patient type for whom relevant modality scan data is available.	***Any patient type for whom relevant modality scan data is***	***Any patient type for whom relevant modality scan data is available.***

	(Substantially Equivalent)	***available.***	
Energy Used and/or Delivered	None – software only application. The software application does not deliver or depend on energy delivered to or from patients *(Substantially Equivalent)*	***None – software only application. The software application does not deliver or depend on energy delivered to or from patients***	***None – software only application. The software application does not deliver or depend on energy delivered to or from patients***
Intended users	Trained radiation oncology personnel *(Substantially Equivalent)*	Designed to be used by ***trained clinicians***	Designed to be used by ***trained clinicians***
Design: Data Visualisation/Graphical User Interface	Contains both an automated processing component and Data Visualisation / Graphical User Interface *(Substantially Equivalent)*	None – the proposed device has no data visualization functionality. All data ***processing is automated*** and does not require user interaction. A control interface is provided for system administration and configuration only	***Yes***.
Design: View manipulation and Volume rendering	Window and level, pan, zoom, cross-hairs, slice navigation, fused views. *(Subject Device functionality is a subset of Predicate Devices)*	None – Not applicable	***Window and level, pan, zoom, cross-hairs, slice navigation***. Maximum or minimum intensity projection (MIP), volume rendering, color rendering, surface rendering, multi-planar reconstruction (MPR), ***fused views***, gallery views.
Design: Image registration	Manual Rigid registration. *(Subject Device functionality is a subset of Predicate Devices)*	Registration for the purposes of replanning/re-contouring and atlas based contouring. The algorithms used for image registration are the same for both predicate and proposed devices.	***Manual and Landmark Rigid***. Automatic multi-modal rigid. Mono-modal and multi-modal deformable registration. Motion correction in hybrid scans and gated scans. Registration for the purposes of re-planning/recontouring and atlas based contouring.
Regions and Volumes of interest (ROI)	Machine learning based contouring and manual ROI manipulation. *(Subject Device*	Atlas Based contouring, registration based re-contouring, ***machine***	2D and 3D ROIs, semi-automatic ROI definition, isocontour ROIs using threshold and

	functionality is a subset of Predicate Devices)	***learning based contouring***	percentage of maximum, one-click seed-pointing contouring, ***manual ROI manipulation***, ROI transformation, Atlas-based contouring.
Design: Region/volume of interest measurements and size measurements	None – not applicable *(Substantially Equivalent)*	***None – not applicable***	Intensity, Hounsfield units, activity and SUV measurements including min, max, mean, peak, standard deviation, total glycolytic activity, median, histogram, max and mean ratio to reference region. Gray for RT Dose. Size measurements include 2D and 3D measurements including rulers and volume, line profile.
Design: Region/Volume Quantification	None – not applicable *(Substantially Equivalent)*	***None – not applicable***	Regions table with charting supports analysis of measurement over multiple studies using standard protocols such as RECIST, PERCIST and WHO
Design: Supported modalities	CT input for contouring or manual registration/fusion. MR, PET input for manual registration/fusion only. DICOM RTSTRUCT for output *(Minor differences)*	**CT, MR**, ***DICOM RTSTRUCT*** for image processing. Any valid DICOM data for data routing	Static and gated ***CT and PET, and static MR,*** SPECT, NM, DICOM RT
Design: Reporting and data routing	No built-in reporting, supports exporting DICOM RTSTRUCT file. *(Minor differences)*	Supports routing and distribution of images to other DICOM nodes including to custom executables determined by the user.	Yes– Distribution of DICOM compliant Images into other DICOM compliant systems. Built-in basic reporting
Compatibility with the environment and other devices	Compatible with data from any DICOM compliant scanners for the applicable modalities. Agent Uploader component compatible with Microsoft Windows.	***Compatible with data from any DICOM compliant scanners for the applicable modalities***. ***Compatible with Microsoft Windows***. Integration with Mirada DBx	***Compatible with data from any DICOM compliant scanners for the applicable modalities***. ***Compatible with Microsoft Windows***. Integration with Mirada DBx application launcher and data browser.

	Cloud-based automatic contouring service compatible with Linux. Web application Server based application compatible with Linux with frontend compatible with all modern web browsers.. *(Minor differences)*	application launcher and data browser	
Communications/Networking	TCP/IP *(Subject Device functionality is a subset of Predicate Devices)*	***TCP/IP*** and SCP	***TCP/IP*** and SCP
Computer platform & operating system	Agent Uploader supporting Microsoft Windows 10 (64-bit) and Microsoft Windows Server 2016. Cloud-based Server based automatic contouring application compatible with Linux. Web application Server based application compatible with Linux with frontend compatible with all modern web browsers. *(Minor differences)*	Server based application supporting Microsoft Windows 10 (64-bit) and Microsoft Windows Server 2016.	Workstation and Server based application supporting Windows Server 2008 R2, SP1 and Windows 7 (64-bit)
Support for radiation treatment planning	AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning *(Subject Device intended use is a subset of predicate devices)*	"Contours generated by Workflow Box may be used as an input to clinical workflows including, but not limited to, radiation therapy treatment planning"	"RTx supports the loading and saving of DICOM RT objects and allows the user to define, import, display, transform, store and export such objects including regions of interest structures and dose volumes to radiation therapy planning systems."

Source for RTx & Workflow Box: (https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181572.pdf, accessed 1/20/2020)

As shown in Table 3, almost all technological characteristics are either substantially equivalent or a subset of the predicate devices' technological characteristics.

5.7. Discussion of differences

Subset of the Predicate Device

The comparison table above shows that several features of AutoContour are a subset of the features of the predicate device. This is because AutoContour's indication for use is narrower in scope than the predicate device in that it is intended only "to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning". The design of AutoContour reflects that narrower scope and the features not shared between AutoContour are such that they can operate independently of the features that are not shared with the predicate devices, and therefore these differences do not create new questions regarding the safety and effectiveness of the device relative to the predicate devices.

Minor differences

The following minor differences exist, but do not represent any significant additional risks or decreased effectiveness for the device for its intended use:

- **Design: Supported modalities:** AutoContour only supports CT image sets as inputs specifically for the contouring feature, while MR and PET image set inputs are only supported for registration purposes. In the predicate devices, all modalities are available for the workflows. This does not affect the safety and effectiveness of the device as it relates to its indications for use as the vast majority of radiation treatment planning is performed on CT images, and where MR or PET modalities are necessary for localization, AutoContour does support manual registration with those modalities which can be used to guide the contouring of the CT image set.
- **Design: Reporting and data routing**: AutoContour does not include reporting features or direct data-routing with DICOM compliant systems - instead AutoContour simply produces a DICOM compliant RT Structure Set file that the user may import into a DICOM compliant treatment planning system. This does not raise new questions regarding the safety and effectiveness of the device since the scope of AutoContour's indication for use is limited to making the contoured structures available for radiation treatment planning purposes and does not include managing or routing of the image data to various systems. The feature of managing or routing of the image data in this way is not a necessary component to achieve this goal, so not having this feature does not affect the safety or effectiveness of the device.
- **Compatibility with the environment and other devices / Computer platform & operating system**: AutoContour utilizes different computer platform & operating system for its 3 components, but this does not raise new questions regarding the safety and effectiveness of the device relative to the predicate device.

5.7. Performance Data

As with the Predicate Devices, no clinical trials were performed for AutoContour. Nonclinical tests were performed according to Radformation's AutoContour Complete Test Protocol and Report, which demonstrates that AutoContour performs as intended per its indications for use. Further tests were performed on independent datasets from those included in training and validation sets in order to validate the generalizability of the machine learning model.

Verification and validation tests were performed to ensure that the software works as intended and pass/fail criteria were used to verify requirements.

5.8. Conclusion

AutoContour is deemed substantially equivalent to the Predicate Devices, Mirada RTx (K130393) & Workflow Box (K181572). Verification and Validation testing and Hazard Analysis demonstrate that AutoContour is as safe and effective as the Predicate Devices. The minor technological differences between AutoContour and the Predicate Devices with regard to the intended use do not raise any questions on the safety and effectiveness of the Subject Device.